HEALTH CARE FINANCING
DRUG PROGRAM
AUGUST, 1999

PANRETIN® TOPICAL GEL 0.1% (9-cis-retinoic acid) (alitretinoin)

PRIOR APPROVAL CRITERIA
Pharmacy obtaines written prior approval.
Physician must provide requested attachments

9-cis-retinoic acid has been approved for Kaposi's Sarcoma (KS), a frequently encountered malignancy in HIV-positive patients. 9-cis-retinoic acid is an isomer of trans-retinoic acid (tretinoin) or Retin-A®.

terms: KS Kaposi's Sarcoma
PRA partial response area
PRH partial response height

Prior Approval Criteria:

1. Panretin is not indicated when systemic anti-KS therapy is required (e.g., more than 10 new KS lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary KS, or symptomatic visceral involvement.) Note. Board approved Retin-A use (via PA) for KS treatment pre-Panretin.

Diagnosis of cutaneous lesions caused by Kaposi's Sarcoma.

Primary number of KS lesions:_____
Estimated total square centimeters :_____

2. 60 day trial period on 0.1% Retin-A gel - by prior approval. If client sustains an improvement of >25% or more from base line (both PRA and PRH){see table 1}, remain on Retin-A gel.

Primary number of KS lesions:_____
Estimated total square centimeters :_____

3. If improvement < 25%, then Panretin may be tried.

4. A thirty (30) day trial period on 0.1% Panretin Gel*. Patient must sustain partial response defined as a 25% or more improvement from baseline for PRA and 25% or more improvement from baseline of PRH before additional coverage is approved. Single 60 gm tube of Panretin gel is approved.

Number of KS lesions :_____
Estimated total square centimeters:_____

5. A sixty (60) day treatment period with Panretin Gel** is approved. Patient must sustain 50% or more improvement from baseline. Four 60 gm tubes cumulative maximum per year.

6. Continued use of Panretin–State of continued improvement

Table 1. ACTG Response Criteria as Applied for Topical Therapy+

Assessment of lesions is limited to only the cutaneous lesions treated. Each lesion assessed for height and diameter. The response evaluation of each KS index lesion will be classified according to the following system:	
Complete Response (CR)	Decrease in lesion area to zero and biopsy documenting absence of KS cells
Clinical complete Response (CCR)	Decrease in lesion area to zero
Partial Response area (PRA)	Decrease in lesion area by 50% or more from baseline without concurrent increase in height of lesion from flat (macular) at baseline to raised (plaque-like or nodular)
Partial Response Height (PRH)	complete flattening of a lesion raised at baseline (decrease in height from nodular or plaque-like to macular) without concurrent increase in lesion area by 25% or more from baseline
Stable Disease (SD)	Lesion does not meet evaluation criteria for CR, CCR, PR, or PD
Progressive Disease (PD)	Increase in lesion area by 25% or more from baseline area, or an increase in height from flat (macular) at baseline to raised (Plaque-like or nodular)

+table 1 supplied by Ligand Pharmaceuticals

notes:

1. 2-8 % of AIDS patients get KS; The widely accepted percentage is 2%.

2.

how supplied	description	AWP	generic name
Panretin 0.1% gel	single 60gm tube	$2,439.31	*9-cis*-retinoic acid
vs.			
Retin A 0.1% gel	single 45gm tube	$ 63.48	*trans*-retinoic acid

(1gm = 1 unit)

*(4) 60gm tubes cumulative maximum per year. (240gm/units/per-year)
*Each tube requires a new prescription from the Physician.